AD_____

Award Number:
W81XWH-08-2-0203

TITLE:
Evaluation of a Yoga Intervention for PTSD

PRINCIPAL INVESTIGATOR:
Sat Bir S. Khalsa, Ph.D.

CONTRACTING ORGANIZATION:
Brigham and Women's Hospital
Boston, MA
02115

REPORT DATE:
April, 2010

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

☒ Approved for public release; distribution unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
01-04-2010	Annual Report	25 SEP 2009 - 24 MAR 2010

4. TITLE AND SUBTITLE
Evaluation of a Yoga Intervention for PTSD

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-08-2-0203

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Sat Bir S. Khalsa, Ph.D.

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Brigham and Women's Hospital

Boston, MA
02115

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
Telemedicine and Advanced Technology Research Center
U.S.Army Medical Research and Material Command
Fort Detrick, MD, 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
There have been no research findings to date.

15. SUBJECT TERMS
yoga, post-traumatic stress disorder

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRMC
U	U	U	UU	5	**19b. TELEPHONE NUMBER** *(include area code)*

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

Table of Contents

Introduction

This report describes the progress on this project on staff recruitment and training, IRB and other administration and subject recruitment to date. Although data has been acquired, it has not yet been analyzed.

Body

Key Research Accomplishments

Staff Recruitment and Training

Kristen Reinhardt was recruited as the research assistant/research coordinator for this project and began full time effort on the project as of March 9, 2009. She was trained in her duties which include IRB administration, subject recruitment, telephone screening, informed consent, subject scheduling, administration of questionnaires, acquisition of electrocardiographic recording techniques and urinary sample collection, and preliminary data management and analysis.

Jennifer Johnston, a Northeastern University clinical psychology graduate student and certified yoga instructor was recruited as the project leader and yoga instructor on this study. Her role includes preparing the yoga curriculum, instructing the yoga classes, managing IRB documentation and performing final data analysis

IRB Administration

An IRB protocol was drafted and reviewed by a representative of the USAMRMC Office of Research Protections (ORP) Human Research Protections Office (HRPO). The IRB protocol was submitted on 3/31/09 to the IRB of Brigham and Women's Hospital and was approved on 5/8/09. The protocol was then submitted to the USAMRMC Office of Research Protections (ORP) Human Research Protections Office (HRPO) on 5/11/09. Following a response to a request for clarifications and revisions from that office on 6/30/09, IRB approval from HRPO was received on 8/12/09. The IRB protocol was submitted on 3/16/2010 for Continuing Review to the IRB of Brigham and Women's Hospital and was approved on 3/22/2010.

Protocol Development

The yoga treatment protocol and manual has been completed in consultation with yoga instructors in the region with experience in instructing yoga to military veterans. The treatment protocol and manual were approved by the IRB on 8/14/09 and by the HRPO on 8/12/09.

Additional Administration

We have submitted an application to the Harvard Catalyst Center for Clinical Investigation for support of the proposed project, which will include partial support of assay costs and use of ambulatory outpatient clinical treatment space. Following a response to a receipt of a request for clarifications on this application, formal support of the study was confirmed in September, 2009.

Following IRB approval, an application was submitted for a Certificate of Confidentiality, which was formally approved on 10/9/09.

The study protocol was submitted to Clinical Trials.gov and was registered on that site as of 8/27/09.

Recruitment

Preliminary research was conducted to identify a list of potential organizations from which military veterans might be recruited and letters of support from those organizations were acquired. Advertising in public media was initiated for subject recruitment in early September, 2009.

As of 3/24/10 we have received 147 inquiries from potential participants, we have conducted 105 telephone screens and we have enrolled 26 subjects.

Protocol Execution

As of 3/24/10, we have had our first cohort of 8 subjects successfully complete the treatment protocol and 7 of them have completed all of the pre- and post-treatment outcome measures. A second cohort of subjects will begin the treatment at the end of April.

Progress Relevant to Statement of Work

All tasks within the Statement of Work have been executed later than anticipated. This was largely due to the fact that although the grant was initiated on 9/25/09, substantial effort on the project, and disbursement of grant funds, did not begin until March of 2009. However, the project is now underway and recruitment and enrollment have been at acceptable levels.

Reportable Outcomes

For the 7 subjects for whom the pre- and post-intervention data is available on the Clinician Administered PTSD Scale (CAPS), the average pre-intervention total score was 77.3 ± 28.6 S.D. and the average post-intervention total score was 51.1 ± 27.6 S.D. A paired t-test indicates a p-value of 0.06.

Conclusions

Although the project is delayed relative to the grant start date, reasonable progress has been made on study startup, recruitment and intervention delivery. Although some data has been acquired, much of it has not yet been analyzed, so there is little data to report at this time, although the preliminary data are supportive of a positive benefit to the subjects.

References

None

Appendices

None